DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration

d1674b

Refer to: CFN 1124798

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

December 16, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Frank Temberino, President
ASCO Eastern Medical Supply
9100 Yellow Brick Road, Suite #4
Baltimore, Maryland 21237

Dear Mr. Temberino:

The Food and Drug Administration (FDA) conducted an inspection of your Waldorf, Maryland facility from December 5 through December 9, 1996. During the inspection, deviations from the Current Good Manufacturing Practice Regulations (CGMP) (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations cause your Oxygen, U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations included the following:

1. Failure to assure that each person engaged in the transfilling of compressed medical oxygen has the education, training, or experience to enable that person to perform the assigned function, and that such training is conducted by qualified individuals on a continuing basis with sufficient frequency to assure employees remain familiar with CGMPs. For example, your employee who performs oxygen transfilling was trained in transfilling in September of 1994, but did not actually perform oxygen transfilling until June of 1996. Furthermore, there was no documentation available to show that additional training had been received during this almost two year period prior to performing actual manufacturing operations. [21 CFR 211.25]

2. Failure to calibrate the vacuum gauges used during transfilling of Oxygen, U.S.P. Your firm fails to document the calibration of the vacuum gauges. [21 CFR 211.160(b)(4)].

3. Failure to establish adequate written production and process control procedures covering all critical aspects of manufacturing operations; for example:

    a. Pre-fill, fill, and post-fill manufacturing operations. In addition, only an audible leak test was performed during the fill operation rather than an appropriate method, such as a soap solution check. [21 CFR 211.100]

b. Calibration of the temperature, vacuum, and pressure gauges. [21 CFR 211.100(a)]

c. Labeling issuance. [21 CFR 211.130(f)]

d. Equipment maintenance. [21 CFR 211.67(c)]

e. Finished product storage. [21 CFR 211.142]

f. Receipt of medical gases. [21 CFR 211.80]

g. Distribution of finished products. [21 CFR 211.150]

h. Complaints and Complaint files. [21 CFR 211.198]

4. Failure to establish batch production records for each batch of Oxygen, U.S.P., including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance. For example, batch production records failed to document the test date and correct lot number, and that venting, color identification, and a heat check were performed on each cylinder filled. Also, batch production records are not identified by the person directly supervising or checking each significant step in the operation. [21 CFR 211.188(b)]

5. Failure to perform adequate pre-fill, fill, and post-fill operations on each high-pressure cylinder filled. For example, batch production records failed to document the correct lot number and test date, and that venting, color identification, and a heat check were performed on each cylinder filled. Also, a post-fill check for leakage was not performed at all. [21 CFR 211.84(d)(3)]

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer.

Sincerely,

William M. Ment

William M. Ment
Acting Director, Baltimore District

Enclosure

cc: Mr. Michael A. Labanowski
ASCO Eastern Medical Supply
3460 Leonardtown Road
Waldorf, MD 20601

bcc: Legal, EI file, HFR-MA1, HFR-MA200, HFR-MA240 (Simmons), HFR-MA250 (Weidman), HFA-224, HFC-210 (CFN 1122795), HFI-35 (purged), HFC-240, HFD-300, HFR-MA2535, HFR-MA295

Mr. Dennis Carroll
Associate Regional Administrator
HCFA
Room 3100
3535 Market Street
Philadelphia, PA 19101 (purged)

Tracking #: 97-BLT-13